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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,921	06/28/2001	Udit Batra	20243CA	1812

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EXAMINER	
SHARAREH, SHAHNAM J	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,921	BATRA ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,26-35 and 37-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,26-35 and 37-47* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/18/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on March 18, 2004 has been entered. Claims 1-16, 26-35, 37-47 are pending. Applicant's arguments are addressed along with the pertinent respective rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-15, 26-35, 37-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makooi in view of Remington: the Science and Practice of Pharmacy 19th edition (pages 1616-1620) (IDS, filed June 28, 2001).

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

Applicant first argues that the presented claims as amended only require a super-disintegrant and do not require a separate disintegrant. In response, Examiner states that contrary to applicant's arguments, the instant inclusive transitional pharase "comprising" does not exclude the use of disintegrants in the compositions of claim 1. so the fact that the claim does not explicitly recite "disintegrant" does not mean that the claimed compositions excludes the use of such compounds.

Moreover, Examiner draws Applicant's attention to page 3, lines 21-27. Accordingly, the term superdisintegrant encompass the use of any disintegrant enumerated in lines 9-13 of the same page. Therefore, the claims as presented still do

not exclude the use of disintegrants unless the transitional phrase of "consisting" is used.

Nevertheless, aside from such arguments, Makooi discloses the use of such super-disintegrants as claimed in the instant 3. For example, col 5, lines 13-16 discloses the use of croscarmelose, carboxymethylcellulose, modified starches and crospovidone. (also see col 3, lines 35-42). Makooi further teaches compressed effavirenz tablets comprising 300mg of efavirenz (50% by wt), sodium lauryl sulfate that is a surfactant, microcrystalline cellulose which is a filler. The use of croscarmelose sodium, lactose and magnesium stearate is also described lubricant (see abstract; col 5, lines 14-50; col 7, lines 15-67; claims 12-15). Makooi teaches higher concentrations of efavirenz of up to 800 mg per tablet (see col 5, lines 36-39; claim 14). Therefore, there is no limitaion in the instant claims that Makooi has not described.

With respect to the compositions of claims 37-47 Examiner has stated that the the claims appear to be drafted as "product by process" claims. Accordingly, products by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113). "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, Makooi's tablets meet the limitations of the instant tablets. Further, Makooi provides for methods of wet granulations in preparing his tablet formulation. (see examples 2-3). The fact that the Makooi uses a wet granulation process is an indication that there still exists an amount of solvent within the mixture during the granulation process. Moreover, water and ethanol are typical solvent systems in a wet granulation process. [1] Thus, the new recitation of solvent systems in amended claims 33, 41 does not overcome the rejection of record, because the fact that Makooi teaches wet granulation is an indication for the use of water and alcohol during his process. Accordingly, the claims stand rejected for the reasons of record.

Declaration Under 37 CFR 1.132

Applicant's statement about the Declaration under 37 CFR 1.132 filed in October 2003 is noted but is not persuasive. Applicant argues that the unexpected results provided can be extrapolated to the entire scope of the generic claims. However, Applicant appears to disregard the general statement made in Makooi about the typical use of superdisintegrants in the art.

Accordingly, super-disintegrants are generally used in the art in amounts of 1% - 10% by weight to provide their effects (see col 3, lines 35-40). Thus, the fact that super-disintegrants can cause disintegration and improve bioavailability at lower concentrations of 10% has been well disclosed in the art and is not an unexpected observation. In fact, optimization of such amounts would have been well achievable by routine experimentation.

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[1] See Michael Aulton, Granualtion pp 365-378, at page 366 last para, Water and other suitable solvents such as ethonal are enumerated as typical solvents used during a wet granulation process. See www.fleshandbones.com/readingroom/pdf/473.pdf.

Rather, in the instant case, Examiner views the unexpected results provided in the Declaration to be due to the combination of the ingredients at their respective amounts as recited in claim 16. The unexpected results thus are only viewed to be sufficient to overcome the rejection of claim 16. Accordingly, the declaration is deemed not to be commensurate with the scope of all other pending claims.

Claim Objection

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

Claim 16 is free of art in view of the unexpected results presented in the declaration under 37 CFR 1.132 filed on Oct 06, 2003.

Conclusion

No claims are allowed. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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